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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,278	11/02/2001	Thomas M. Jessell	40314-A/JPW/MVM	3060

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
O HARA, EILEEN B	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,278	JESSELL ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19,20,22-27 and 36-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17, 19, 20, 22-27 and 36-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17, 19 and 41-48, drawn to dorsalin-1 polypeptides, classified in class 530, subclass 350 for example.

II. Claim 20, drawn to a method for stimulating neural crest cell differentiation comprising contacting a neural crest cell with a dorsalin-1 polypeptide, classified in class 424, subclass 185.1, for example.

III. Claim 22, drawn to a method for regenerating nerve cells in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

IV. Claim 23, drawn to a method for promoting bone growth in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

V. Claim 24, drawn to a method for promoting wound healing in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

VI. Claims 25-27, drawn to a method for treating a neural tumor in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

VII. Claims 36-38 and 40, drawn to an antibody to dorsalin-1 polypeptide, classified in class 530, subclass 388.22, for example.

VIII. Claim 39, drawn to a method for inhibiting the activity of dorsalin-1 polypeptide in a subject comprising administering an antibody to dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptides of invention I are related to the antibodies of invention VII by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein.

Inventions I and inventions II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in a method of making and purifying antibodies, which is a materially different method from those of methods II-VI.

Inventions II-VI are related in that they all require dorsalin-1 polypeptide, however the

methods are patentably distinct because they are different methods of treatment having different results and goals.

Inventions VII and invention VIII are related as product and process of use. In the instant case the antibodies are used in the method for inhibiting the activity of dorsalin-1 in a subject, but the antibodies can also be used in a method of purifying the protein, which is a materially different method.

Invention I and invention VIII are related as a process of making and a process of using a common product. The polypeptides of invention I are the cognate antigens necessary for production of the antibody of invention VII which is used in the method of inhibiting the dorsalin-1 of invention VIII, but the polypeptides may also be used in a method of treatment, which is a materially different method.

Inventions VII and inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody to dorsalin-1 polypeptide is not used in the methods of inventions II-VI.

Invention VIII is unrelated to each of inventions II-VI. The invention of method VIII requires antibody to dorsalin-1 polypeptide, while the invention of methods II-VI require the dorsalin-1 antibody.

Further Restriction Within Groups I-VIII

3. Applicants' claims are drawn to two patentably distinct dorsalin-1 polypeptides, chick dorsalin-1 (SEQ ID NO: 2) and mouse dorsalin-1 (SEQ ID NO: 9). These proteins are patentably distinct because they have significantly different amino acid sequences (427 amino acids for SEQ ID NO: 2 and 257 amino acids for SEQ ID NO: 9), and would require separate searches. Therefore, antibodies to the two different proteins are also different and patentably distinct, and the methods of using the two polypeptides or antibodies are also patentably distinct and would require different search and consideration. Applicant is required to elect a single invention of a dorsalin-1 polypeptide, antibody or method of treatment.

Applicant is advised that this is not a species election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter and/or the need for non-coextensive literature search and/or separate sequence database searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER